

REMARKS

Claims 1-15, as amended, appear in the application for the Examiner's review and consideration. Claims 2 and 15, which were indicated as being allowable but which were objected to for being dependent upon a rejected base claim, have been written in independent form and are now believed to be in condition for allowance. Claim 1 has been amended to recite that the co-solvent is present in an amount of about 17% or less, support for which is present in the specification as originally filed and in particular, in the example. As no new matter has been introduced by these amendments, their entry at this time would be appreciated to reduce the issues for appeal.

Claims 1, 5-7, and 9-11 are again rejected under 35 U.S.C. § 102(b) as being anticipated by Wolf (U.S. Patent No. 4,835,002). Applicants again respectfully traverse this rejection.

Claim 1 of the present application recites an edible, clear, high oil loaded, thermodynamically stable oil-in-water microemulsion comprising:

- (a) at least 30% of oil;
- (b) 1 to 30% of a non-ionic surfactant system having a hydrophilic lipophilic balance, HLB, comprised between 9 and 18;
- (c) *about 17% or less of co-solvent*; and
- (d) at least 30% of water.

The co-solvent, when present, resides in the aqueous phase and is typically an alcohol selected from the group consisting of propylene glycol, ethanol, mono and disaccharide sugars and sugar alcohols such as sorbitol, xylitol and mannitol. The high oil content of the claimed presently claimed invention is highly advantageous in the flavor industry as it can be used to retain greater amounts of lipophilic flavoring components.

In contrast, the microemulsions disclosed in Wolf are formed with:

- (a) about 0.01 to 45% of oil, preferably about 1 to 15% (i.e., lower than claimed);
- (b) about 0.1 to 30% of a surfactant composition, preferably about 1 to 30%;
- (c) *about 20 to 95% of a polyol* (i.e., a co-solvent) and preferably about 25 to 80% (i.e., higher than claimed herein); and
- (d) the balance being water. (col. 7, lines 53-59)

As stated in the description, the alcohol or polyol used in the Wolf compositions do not function as co-surfactant; it is only essentially present in the outer water phase and not in the

inner oil phase of the microemulsions (col. 4, lines 37-47). In other words, the alcohol is a "co-solvent" as is commonly referred in the art.

One major difference between Wolf and the present invention is that Wolf's emulsions comprise 20% or more of a co-solvent, namely an alcohol. As noted in Wolf, alcohols suitable for this purpose are preferentially soluble in water (col. 4, line 23), and the last step of the method for forming the microemulsions consists of adding "enough of the alcohol to achieve the microemulsion stage, as evidenced by the clarity, to the naked eye, of the resulting system" (col. 7, lines 37-39). Wolf further states that "Prior to the addition of the full amount of alcohol needed to achieve such clarity, the mixture of [surfactant and oil] will have a cloudy and turbid appearance" (column 7, lines 39-42). It is clear then that the full amount of alcohol, constituting at least 20% or more of the composition, is essential in obtaining a clear microemulsion according to Wolf. Thus, the prior art teaches the minimum amount of co-solvent required to obtain a microemulsion is at least 20%, but there is no teaching of how to obtain a clear emulsion using less than that amount, nor is there any disclosure or suggestion that less than 20% alcohol could be used to obtain a clear product.

In contrast, one of the novel features of the present invention is that its microemulsion may include a high amount of oil and be stable at high temperature, even with a low ratio of co-solvent relative to surfactant. In specifying that using less than the minimum amount of alcohol required would lead to a cloudy and turbid product, Wolf does not teach, disclose or suggest that a clear, high oil loaded, thermodynamically stable oil-in-water microemulsion can be obtained with less than 20% alcohol.

To make the current rejection, the Examiner must be interpreting Wolf as disclosing or teaching that slightly below 20% of the alcohol can be used to form suitable emulsions, but this rejection is no longer applicable since claim 1 has been amended to recite that the co-solvent is present in an amount of about 17% or less to avoid any overlap over Wolf's minimum amount of about 20%. Applicants maintain their disagreement that Wolf discloses amounts lower than disagree with the Examiner's allegation that Wolf's disclosure of "about 20% polyol" reads on amounts that are slightly less than 20%. More particularly, applicants respectfully traverse the Examiner's objection based on the reasoning that column 8, lines 13-15 is a teaching for the use of lower amounts of polyol. That portion of Wolf generally states that when more polar solvents are used, less of the polyol can be used, and the Examiner has utilized this a teaching that supports an extrapolation of the concentration range of the polyol to below 20%. But such an interpretation is not supported by Wolf's disclosure, nor would it be ascertainable by a skilled artisan.

Wolf's specification first cites the amounts of components that are suitable for the preparation of microemulsions, and mentions in particular a large range for the concentration of polyol, varying from 20 to 95% and preferably at least 25% or more of the microemulsion (column 7, lines 52-58). Later in the text, in column 8, a separate paragraph states that the polarity of the alcohol used will have an impact on the proportions needed to obtain a clear microemulsion and more particularly, that more polar solvents will be used in lower proportions than less polar solvents. But there is no further disclosure, figure or other explanatory information in Wolf to illustrate the variation in the alcohol proportions required as a function of its polarity. A person of ordinary skill in the art would normally consider that the wide range of alcohol concentration described in column 7 encompasses the entire scale of polarity. To clarify this point, however, examples or other disclosure should have been provided and the omission of the use of lower amounts of polyol from Wolf is telling.

All examples of Wolf's patent are based on the use of a single alcohol, namely propylene glycol which is, according to the polarity scale, the less polar alcohol. The proportions of propylene glycol exemplified in the Wolf document vary between a minimum of 47% and a maximum of 82% by weight of the microemulsions. These proportions are close to the upper limit of polyol amount cited by Wolf and do not illustrate the complete range of concentration that is described in column 7. Moreover, the statement according to which more polar alcohols could be used in lower proportions is not exemplified. In fact, no order of magnitude is given as regards the suitable proportions for other ingredients than propylene glycol. The sentence according to which "more polar alcohol will be used in lower amount compared with propylene glycol", is therefore not well defined, this amount being theoretically able to vary between 20% (minimum of alcohol described) and 47% (minimum of propylene glycol exemplified) which constitutes a vague large range. Therefore as amounts lower than 47% of alcohol are not even exemplified, applicants respectfully disagree with the Examiner's conclusion that amounts lower than 20% (minimum described) are expressly or inherently disclosed, taught or even suggested by Wolf.

On the other hand, Wolf expressly teaches that the alcohol has to be added in an amount "enough to achieve the microemulsion stage, as evidence by clarity, to the naked eye, of the resulting system" and specifies furthermore that "prior to the addition of the full amount of alcohol needed to achieve such clarity, the mixture of [other ingredients] will have a cloudy or turbid appearance". The importance of adding the full amount of alcohol is thus clearly outlined by the specification. Now, as mentioned above, a skilled person in the art, looking at the examples, would be taught that at least 47% of propylene glycol are used and

lead to a clear product. Even if 20% alcohol is described as the lowest possible amount of this ingredient, there is no evidence that this would provide a clear product or that a lesser amount of polyol should or could be used. There is also no suggestion or motivation to use any amounts of alcohol in the lower end of the disclosed range. This is also inconsistent with the express teaching of a preferred range of alcohol concentration that is comprised between 25 and 80% by weight.

In contrast, the present invention is in particular based on the fact that the amounts of surfactant and co-solvent have been advantageously minimized, and the applicant claims microemulsions wherein the amount of co-solvent is specifically present in proportions lower than 20% of the dispersion. The examples given in the present application disclose, as in Wolf, the use of propylene glycol as co-solvent, and illustrate the difference existing between the document from the prior art and this invention, as this alcohol (the less polar on the scale given by Wolf) is used in amounts lower than 20% by weight relative to the total weight of the microemulsion, while Wolf uses more than 45% of it in all examples.

The main advantage provided by the use of a minimum amount of co-solvent in the microemulsions claimed by the present application, lies in the possibility to get higher loadings in oil in the microemulsions. In fact, as claimed and exemplified, the products of the present invention comprise more than 30% by weight of oil, which constitute of course an advantage of paramount important in the flavor industry.

Comparatively, although Wolf pretend in his description that amounts of oil varying from 0.01 to 45% by weight could be obtained, only amounts as high as 9.7% oil are exemplified. Applicants also draw the attention of the Examiner to the fact that the claim scope of the Wolf patent is limited to an amount of oil of 25%, and the preferred maximum amount of oil is only 10%. The differences existing between the breadth of the ranges described by Wolf and the narrowness of the exemplified ranges are important, considering that it is part of the general knowledge of a skilled person in the art that the selection of components for a microemulsion and the appropriate amounts to use are very critical and limited to first obtain a microemulsion and second obtain a microemulsion which is stable for a reasonable amount of time (S.E. Friberg, J. Dispersion Science & Technology, Vol. 6, N°3, p 320). Thus, the concentrations of polyol and oil near the extreme ends of the disclosed amounts, as relied upon by the Examiner to reject the claims, are so far from the exemplified ones and the core teachings of the Wolf patent, would not teach the skilled artisan how to arrive at the present invention and cannot be considered as anticipating or disclosing the features of the presently claimed invention. Since Wolf does not teach each and every

element of the present claims, Applicants respectfully submit it cannot anticipate these claims. Accordingly, the § 102(b) rejection should be withdrawn.

Similarly, Wolf does not render the present claims obvious. The Examiner rejects claims 1 and 3-14 under 35 U.S.C. § 103(a) as being unpatentable over Wolf, but because of the significant difference between the present invention and the Wolf composition, such as the amount of co-solvent used to produce a clear microemulsion, Wolf cannot render these claims obvious. In fact, by disclosing that using less than the minimum amount of alcohol required would lead to a cloudy and turbid product, Wolf teaches away from the present invention. A person skilled in the art, confronted with the problem of providing a clear and stable microemulsion, would have no motivation to modify Wolf to prepare a product as claimed in the present invention.

The Examiner further states that, although claims 3 and 4 appear to differ from Wolf in that an antioxidant, such as a tocopherol, is used, using an antioxidant in any food product would have been an obvious way to enhance the storage life of a food product and to fortify a food product. As to claim 13, the Examiner states that flavor enhancement would be expected from the inclusion of a flavor or an added flavor to the beverage product of Wolf, and, as to claim 8, that selecting the specific alcohols of claim 8 for use in Wolf would have been obvious to a skilled artisan with respect to the use of sugar alcohols. However, these rejections are rendered moot because, as explained above, the microemulsion of claim 1 is fundamentally different from the Wolf composition and is not obvious in light of Wolf. Hence, § 103 rejection should also be withdrawn.

In view of the foregoing, it is believed that the entire application is now in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, a personal or telephonic interview is respectfully requested to discuss any remaining issues in order to expedite the eventual allowance of the claims.

Respectfully submitted,

Date

6/9/04


Allan A. Fanucci ^{36,256}
(Reg. No.)

WINSTON & STRAWN LLP
CUSTOMER NO. 28765
(212) 294-3311